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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

ACCORD HEALTHCARE, INC. USA,  
ACCORD HEALTHCARE, INC., and  
INTAS PHARMACEUTICALS LTD.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR  
PATENT INFRINGEMENT**

**(Filed Electronically)**

Plaintiff Merck Sharp & Dohme Corp. (“Merck”) for its Complaint against Defendants Accord Healthcare, Inc. USA and Accord Healthcare, Inc. (together, “Accord”), and Intas Pharmaceuticals Ltd. (“Intas”) (collectively, “Defendants”) hereby allege as follows:

### **THE PARTIES**

1. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Upon information and belief, Defendants Accord are corporations organized under the laws of North Carolina, with a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

3. Upon information and belief, Defendant Intas is a corporation organized under the laws of India, with its principal place of business at Chinubhai Centre Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

4. Upon information and belief, Defendants Accord are wholly-owned subsidiaries and agents of Intas.

5. Upon information and belief, the acts of Accord complained of herein were done at the direction of, with the authorization of, and with the cooperation, the assistance, the participation of, and at least in part for the benefit of, Intas.

### **JURISDICTION AND VENUE**

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

8. Upon information and belief, Accord manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

9. Upon information and belief, Accord is licensed to do business with the New Jersey Department of Health and Senior Services as a “Manufacturer” of pharmaceuticals in the State of New Jersey, registration No. 5003815.

10. Upon information and belief, Accord has previously submitted to the jurisdiction of this Court, including in *Astrazeneca Pharmaceuticals LP, et al. v. Accord Healthcare, Inc., et al.*, Civil Action No. 08-4804 (JAP)(TJB), *Astrazeneca Pharmaceuticals LP v. Accord Healthcare, Inc., et al.*, Civil Action No. 09-0619 (JAP)(TJB), *Hoffmann-La Roche Inc. v. Accord Healthcare, Inc., et al.*, Civil Action No. 11-1192 (ES)(CLW), and *Hoffmann-La Roche Inc. v. Accord Healthcare, Inc., et al.*, Civil Action No. 11-3663 (ES)(CLW), and has availed itself of the legal protections of the State of New Jersey, including having asserted counterclaims in this jurisdiction.

11. This Court has personal jurisdiction over Accord based upon, *inter alia*, its connection with and sales in this District.

12. Upon information and belief, Intas manufactures and/or distributes through Accord generic drugs for sale and use throughout the United States, including in this Judicial District.

13. Upon information and belief, Intas has previously submitted to the jurisdiction of this Court, including in *Astrazeneca Pharmaceuticals LP, et al. v. Accord Healthcare, Inc., et al.*, Civil Action No. 08-4804 (JAP)(TJB), *Astrazeneca Pharmaceuticals LP v. Accord Healthcare, Inc., et al.*, Civil Action No. 09-0619 (JAP)(TJB), *Hoffmann-La Roche Inc. v. Accord Healthcare, Inc., et al.*, Civil Action No. 11-1192 (ES)(CLW), and *Hoffmann-La*

*Roche Inc. v. Accord Healthcare, Inc., et al.*, Civil Action No. 11-3663 (ES)(CLW), and has availed itself of the legal protections of the State of New Jersey, including having asserted counterclaims in this jurisdiction.

14. Upon information and belief, Accord's license to do business with the New Jersey Department of Health and Senior Services as a "Manufacturer" of pharmaceuticals in the State of New Jersey, registration No. 5003815, identifies Intas as a parent company of Accord.

15. This Court has personal jurisdiction over Intas based upon, *inter alia*, its connection with and sales in this District.

#### **CLAIM FOR RELIEF**

16. Merck is the holder of New Drug Application ("NDA") No. 22-023, by which the United States Food and Drug Administration ("FDA") granted approval for single dose glass vials containing sterile lyophilized powder of fosaprepitant dimeglumine for intravenous use after reconstitution and dilution, in 115 mg and 150 mg dosage strengths. Fosaprepitant dimeglumine described in Merck's NDA is indicated, *inter alia*, for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and to prevent nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Merck markets the single dose glass vials in the United States under the tradename "EMEND<sup>®</sup> (fosaprepitant dimeglumine) for Injection" ("EMEND<sup>®</sup> IV").

17. Merck owns United States Patent No. 5,691,336 ("the '336 patent"), which was duly and legally issued by the United States Patent and Trademark Office ("USPTO")

on November 25, 1997, and is titled “Morpholine compounds are prodrugs useful as tachykinin receptor antagonists.” A copy of the ’336 patent is attached as Exhibit A.

18. Merck owns United States Patent No. 5,716,942 (“the ’942 patent”), which was duly and legally issued by the USPTO on February 10, 1998, and is titled “Treatment of migraine with morpholine tachykinin receptor antagonists.” A copy of the ’942 patent is attached as Exhibit B.

19. Upon information and belief, Accord submitted to the FDA Abbreviated New Drug Application No. 204025 (“ANDA”) seeking approval to manufacture, use, and sell single dose vials containing fosaprepitant dimeglumine for injection, 150 mg/vial dosage strength (“the Accord ANDA product”) prior to the expiration of the ’336 patent. Upon information and belief, Accord’s ANDA contains a certification with respect to the ’336 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Accord has not submitted to the FDA an Abbreviated New Drug Application with respect to a 115 mg dosage strength fosaprepitant dimeglumine for injection product.

20. Upon information and belief, Intas actively and knowingly directed, induced, participated in, assisted with, contributed to, and/or aided and abetted the submission to the FDA of ANDA No. 204025.

21. Accord and Intas, by their counsel, sent a letter dated April 25, 2012 (“Accord Notice Letter”) to Merck, which was delivered thereafter, in which Accord represented that it had filed an ANDA for the Accord ANDA product containing a certification with respect to the ’336 patent, and that it sought approval of its ANDA prior to the expiration of the ’336 patent.

22. This action was commenced within 45 days of the date of the Accord Notice Letter.

**FIRST COUNT**  
**INFRINGEMENT BY ACCORD AND INTAS OF U.S. PATENT NO. 5,691,336**

23. Plaintiff re-alleges paragraphs 1-22 as if fully set forth herein.

24. By seeking approval of Accord's ANDA No. 204025 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '336 patent before its expiration including its patent term extension, Accord and Intas have infringed the '336 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Accord ANDA product, if approved by the FDA, prior to the expiration of the '336 patent including its patent term extension, would infringe the '336 patent under 35 U.S.C. § 271. Merck is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Accord's ANDA No. 204025 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '336 patent to which Merck is or becomes entitled.

26. Plaintiff will be irreparably harmed by Accord and Intas's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

27. Upon information and belief, Accord and Intas were aware of the existence of the '336 patent and were aware that the filing of the ANDA and certification with respect to the '336 patent constituted an act of infringement of that patent.

**SECOND COUNT**  
**INFRINGEMENT BY ACCORD AND INTAS OF U.S. PATENT NO. 5,716,942**

28. Plaintiff re-alleges paragraphs 1-27 as if fully set forth herein.

29. By seeking approval of Accord's ANDA No. 204025 to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '942 patent before its expiration, Accord and Intas have infringed the '942 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Accord ANDA product, if approved by the FDA, prior to the expiration of the '942 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '942 patent. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Accord's ANDA No. 204025 be a date that is not earlier than the expiration of the '942 patent, or any later expiration of exclusivity for the '942 patent to which Merck is or becomes entitled.

31. Plaintiff will be irreparably harmed by Accord and Intas's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

32. Upon information and belief, Accord and Intas were aware of the existence of the '942 patent and were aware that the filing of the Accord ANDA constituted an act of infringement of that patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment be entered that Defendants have infringed the '336 and '942 patents by submitting the aforesaid ANDA;

B. Preliminary and permanent injunctions be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs, or from inducing and/or encouraging the use of methods, claimed in the '336 and '942 patents;

C. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 204025 be a date that is not earlier than the expiration of the '336 and '942 patents, including any extensions thereof and any later expiration of exclusivity for those patents to which Merck is or becomes entitled;

D. An Order be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

E. Such other and further relief as the Court may deem just and proper.

Dated: June 1, 2012

By: s/ Charles M. Lizza

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 and 40.1**

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding except for the matter captioned, *Merck Sharp & Dohme, Corp. v. Sandoz Inc.*, Civil Action No. 12-3289 (PGS)(LHG), which involves the same plaintiff and alleges infringement of the same patents at issue in the above-captioned action.

Dated: June 1, 2012

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